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Patenting Resources: Biotechnology and the Concept of Sustainable Development

YVONNE CRIPPS*

I. DEFINITIONS

The World Commission on Environment and Development has defined "sustainable development" as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs."¹

Biotechnology has already produced arguably beneficial agricultural developments,² and it may eventually prove to have an important role in the sustainable use of resources.³ Claims that it will provide a key to sustainable development, particularly in developing countries,⁴ should, however, be treated with great caution.

Developing countries seek to develop as quickly and efficiently as possible while preserving their natural resources, culture and traditions, and that goal is compatible with, and indeed conducive to, protecting the global environment from the effects of numerous isolated industrial revolutions. In that sense, it might be thought to be in the best interests of developed and developing nations that the developing nations have easy access to so-called environmentally sound technologies.⁵

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1. WORLD COMM'N ON ENV'T & DEV., OUR COMMON FUTURE 43 (Oxford University Press, 1987).

2. See Les Levidow & Joyce Tait, *The Greening of Biotechnology: GMO's as Environment-Friendly Products*, 18 SCI. & PUB. POL'Y 271 (1991).

3. See WALTER V. REID ET AL., BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT (1993).

4. See, e.g., Klaus M. Leisinger, *Sociopolitical Effects of New Biotechnologies in Developing Countries*, Food, Agriculture and the Environment Discussion Paper 2 (Int'l Food Pol'y Research Inst., Mar. 1995).

5. Chapter 34 of the United Nations Agenda 21 provides the following definition of environmentally sound technologies: 34.1. Environmentally sound technologies protect the environment, are less polluting, use all resources in a more sustainable manner, recycle more of their wastes and products, and handle residual wastes in a more acceptable manner than the technologies for which they were substitutes.

United Nations Conference on Environment and Development, Agenda 21: Programme of Action for Sustainable Development, ch. 34, U.N. Doc. A/Conf. 151/4 (1992). For a critique of this definition and any formal definition, see Gaëtan Verhoosel, *Beyond the Unsustainable Rhetoric of Sustainable Development: Transferring Environmentally Sound Technologies*, 11 GEO. INT'L ENVTL. L. REV. 49, 62-65 (1998).

Yet such technologies tend to be in the hands of private parties who have a strong interest in the protection of intellectual property rights (IPRs).⁶ The private sector has traditionally found little incentive for giving its newest technology to developing countries at a discount. The fear that intellectual piracy will reduce profit lessens the likelihood that companies will invest substantially in developing nations unless a system of IPR protection is in place.⁷ Since private parties control the majority of technologies, and since public institutions find it increasingly difficult to compete with the resources and research of these parties, corporate interest in IPR protection has impeded the creation of an effective method of transfer.

The interests of the developing nations in retaining their present resources and developing them in traditional ways,⁸ while still receiving help from the developed nations, also work against the wide-ranging IPR protection that the developed countries desire⁹ in the sense that IPR protection threatens to place prohibitive costs on materials and processes that indigenous peoples in developing countries are already using. Even where indigenous cultures can afford to purchase protected materials, further development and exploitation by traditional means are

6. See Joan Magretta, *Growth Through Global Sustainability: An Interview with Monsanto's CEO, Robert B. Shapiro*, 75 HARV. BUS. REV. 79, 87-88 (1997).

7. See Beata K. Smarzyska, *Composition of Foreign Direct Investment and Protection of Intellectual Property Rights in Transition Economies* 19 (1998) (presented at Yale-Tubingen Summer Seminar on Transition Economies and Ph.D. Conference at Columbia University), at http://www1.worldbank.org/wbiep/trade/papers_2000/IPRarticle.pdf.

We . . . find that a weak IPR regime has a negative impact on foreign investment inflows. . . . It not only deters [foreign direct investment] in general but it also discourages foreign investors from undertaking local production. . . . The negative effect of inadequate IPR protection is particularly strong in four technology-intensive sectors: drugs, cosmetics and health care products; chemicals; machinery and equipment; and electrical equipment.

Id.

8. See General Council, *Preparations for the 1999 Ministerial Conference: Proposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities: Communication from Bolivia, Columbia, Ecuador, Nicaragua and Peru*, WTO WT/GC/W/362 (Oct. 12, 1999) (delivered by the Permanent Mission of Peru in preparation for the 1999 Ministerial Conference of the WTO.). See generally Michael D. Coughlin, Jr., *Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity*, 31 COLUM. J. TRANSNAT'L L. 337 (1993); *Diversa Signs First Agreement Granting Access to Biodiversity in Africa* (2000), at http://www.diversa.com/presrele/2000/view_release.asp?id=20001207; *Diversa Corporation Signs Biodiversity Access Agreement Gaining Discovery Rights in Alaskan Wilderness* (2000), at http://www.diversa.com/presrele/2000/view_release.asp?id=20000810.

9. An interest which, as we shall see, is reflected, *inter alia*, in article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, 93-94 (1994) [hereinafter TRIPS Agreement], available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

often excluded by the IPRs of others.¹⁰ But is the concept of sustainable development relevant only to the agricultural and horticultural spheres?

II. AGRICULTURE AND BEYOND

The emphasis in discussions of sustainable development has, until now, been on agriculture. Although Amartya Sen has provided cogent evidence that feeding the peoples of the world is more a problem of distribution than production,¹¹ it has been suggested that genetically engineered crops will reduce hunger and the likelihood of famine.¹² The much-publicized genetically engineered “golden rice” contains a higher proportion of vitamin A than its non-engineered counterparts¹³ and this enriched grain has been claimed as a major step towards eradicating vitamin A deficiencies in developing countries.¹⁴ Yet in January 2001, Gordon Conway, the President of the Rockefeller Foundation, which financed the original research on golden rice, called for restraint in what was being claimed in terms of its advantages over conventional rice.¹⁵ His wise warning came at a time when scientists not directly involved in the research were pointing out that a person would need to consume fifteen pounds of the golden rice per day to ingest the recommended minimum daily intake of vitamin A.¹⁶ Several varieties of rice have now been patented, including Basmati rice,¹⁷ and there are seventy patents relating to golden rice in the hands of thirty-two patent holders, including several

10. See generally S.M. Mohamed Idris, *Doublespeak and the New Biological Colonialism*, in *A COURSEBOOK IN INTERNATIONAL INTELLECTUAL PROPERTY* 1052, 1052-53 (Doris Estelle Long & Anthony D’Amato eds., 2000) (describing the effect on Indian farmers of patent protection for genetically altered seeds); *Welcome to Biocolonial Times: Ayahuasca*, *supra* at 1056 (describing the effect on indigenous Amazonian peoples of patent protection for traditional medicines).

11. See AMARTYA SEN, *RESOURCES, VALUES, AND DEVELOPMENT* 452-80 (1984).

12. See ROYAL SOC’Y OF LONDON, ET AL., *TRANSGENIC PLANTS AND WORLD AGRICULTURE* (2000), available at <http://www.nap.edu/html/transgenic/need.html>.

It is important to increase yield on land that is already intensely cultivated. However, increasing production is only one part of the equation. Income generation, particularly in low-income areas, together with the more effective distribution of food stocks, are equally, if not more, important. GM technologies are relevant to both these elements of food security.

Id.

13. *Vitamin Rich Swiss Rice to Arrive in India Soon*, *TIMES OF INDIA*, Feb. 15, 2001, available at <http://www.timesofindia.com/today/15hlth20.htm>.

14. See Mary Lou Guerinot, *The Green Revolution Strikes Gold*, 287 *SCIENCE* 241, 241-43 (2000).

15. Letter from Gordon Conway, President of the Rockefeller Foundation, to Greenpeace on the Issue of “Golden Rice” (Jan. 22, 2001), at http://208.240.92.21/news/012201_lettergreenpeace.html.

16. Michael Pollan, *The Great Yellow Hype*, *N.Y. TIMES MAG.*, Mar. 4, 2001, at 15, 15-16.

17. U.S. Patent No. 5,663,484 (issued Sept. 2, 1997).

multinational companies. A golden rice indeed—but perhaps more for patent holders than potential consumers.

Genetically engineered crops with improved nitrogen uptakes that reduce the need for heavy applications of fertilizer have been developed, and there are new pest and herbicide resistant crops,¹⁸ though even in the latter context there are paradoxes in terms of sustainability. The herbicide resistant crops may lead to increased environmental pollution and increased risks to human health as herbicides can be applied broadly and in significant quantities across wide areas without fear of damage to the crops in question. This is likely to increase human uptake of these substances. It should also be noted that the pest resistant crops often fail to distinguish between harmful and ecologically desirable insects,¹⁹ and thus cause imbalances in ecosystems. Then there is the problem of antibiotic resistance in humans. This has been linked to the frequent use by genetic engineers of antibiotic resistance markers as a means of selection of certain genetic materials in bacteria that may then affect humans through the food chain.²⁰ And although the importance of variety in nature (biodiversity) is well understood, genetic engineering tends to lead to the use of fewer varieties in favor of those deemed most efficient. Monoculture greatly enhances risks from pests and disease.²¹ The blight-induced Irish potato famine of the nineteenth century stands as a warning against the use of one or a few favored varieties. In the latter years of the twentieth century Dutch Elm disease destroyed a very significant proportion of European elms as the Dutch elm had been overwhelmingly the elm of choice. Ironically, however, there are now reports that genetic engineers have produced elms that are genetically engineered to be resistant to disease.²²

It is also somewhat paradoxical that international *patent* depositories, governed by the Budapest Convention,²³ may in the future, along with the extensive collections of zoological gardens such as those in New York and

18. See Les Levidow & Susan Carr, *Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA*, 11 RISK: HEALTH, SAFETY & ENVT. 9, 9-10 (2000).

19. See Angelika Hilbeck et al., *Effects of Transgenic Bacillus thuringiensis Corn-fed Prey on Mortality and Development Time of Immature Chrysoperla carnea (Neuroptera: Chrysopidae)*, 27 ENVTL. ENTOMOLOGY 480 (1998) (analyzing the similar effect of transgenic plant varieties on target pest and nontarget pest species).

20. See generally George Sundin, *Antibiotic Resistance Affects Plant Pathogens*, 291 SCIENCE 2551, 2551 (2001).

21. See generally JACK DOYLE, *ALTERED HARVEST: AGRIC., GENETICS, AND THE FATE OF THE WORLD'S FOOD SUPPLY* (1985) (providing a general outline of developments in modern agriculture and the possible repercussions).

22. See Gillian Harris, *GM Elms "Immune to Killer Disease"*, LONDON TIMES, Aug. 28, 2001, at 7.

23. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, *opened for signature* Apr. 28, 1977, 32 U.S.T. 1241, 17 I.L.M. 285 (entered into force Aug. 19, 1980).

London, provide a means by which biotechnologists can recreate as well as analyze specimens from extinct species. These collections of biological material gathered either in conjunction with the patent system or for the purposes of research could well become an invaluable resource in the future, especially in the battle against extinction of species.²⁴ This is biotechnology as preservation and, in the future, reconstruction. Nor is it too futuristic to consider whether we are entering an era in which any debate on sustainable development will encompass subject matter that extends well beyond the agricultural and even the zoological.

A. The Sustainable Development of Humans

Medical scientists might claim that they are working on the refinement or sustainable development of human beings. But at what point does a developed or sustainable human cease to be human? And at what point does engineering or development of human beings or the use of them or their parts as resources alter our definition and perceptions not only of sustainable development but also of what it is to be human?

Genetic engineers now have the means to alter the natural course of evolution much more rapidly and in much more extreme ways than was previously possible. Thus transgenic animals have been produced, including pigs and other animals carrying human genes.²⁵ The European Patent Office (EPO) has received many patent applications for these partly animal and partly human chimeras.²⁶ Consider also that the latest developments in the unraveling of the human genome bring news that the human genome differs considerably less than had been thought from that of the earthworm and other species. All the more slight then the difference between the human genome and that of the chimpanzee, especially in the light of knowledge of the many species of animal already engineered with human genes. We should not doubt that existing legal definitions of life, humanity

24. See generally Robert Mazurek, *Back from the Dead*, NEW SCIENTIST, Sept. 10, 1999, at 40 (discussing the possibility of cloning endangered species).

25. Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality Into European Union Biotechnology Patent Law*, 19 BERK. J. INT'L L. 1, 6 (2001).

26. See *id.* at 5.

From the early 1980s through the beginning of 1998, the European Patent Office (EPO) received a total of 15,000 patent applications for biotechnological inventions. Of these, roughly 4,000 concern genetic engineering, approximately 1,000 are for transgenic plants, about 500 are for transgenic animals, and over 2,000 relate to DNA sequences isolated from the human genome that are used to develop therapies and medicines.

Id.

and personality will soon be severely tested. At the same time, some of these newly developed creatures hold out great promise of medical breakthroughs, and they are of particular interest to this conference because so many biotechnological developments aim at a goal of sustainability through renewability.

B. Clones as Renewable Resources

Stem cell research and the advent of Dolly the sheep have brought cloning into the arena of public debate. Animals have, however, been cloned since the early 1960s²⁷ and humans since the early 1990s,²⁸ the latter by the use of techniques of embryo splitting less spectacular than the nuclear transfer technique which cloned Dolly from an adult somatic cell. Although still extremely unreliable as a technique,²⁹ the "Dolly" method of cloning was a scientific breakthrough of immense significance in mammals, not least in terms of its implications for demographics and reproduction. Conventional notions of fertility and reproductive age now require redefinition.

As already noted, humans have been cloned since the early 1990s by in vitro fertilization specialists using a technique of embryo splitting.³⁰ In the light of recent debates about cloning, one might have thought that this particular facet of in vitro fertilization work would have been highly controversial, but it has in fact largely escaped notice, and therefore comment, by non-scientists.³¹ These split embryos would, after implantation, gestation and birth, grow up as identical twins. It is only recently, however, that Professor Antinori, an Italian scientist, has announced that he will clone a human being³² *by the Dolly method*, that is, from an adult somatic cell. In this way, for example, a clone could be produced from one of the somatic cells of a man, or of a woman beyond conventional

27. See, e.g., J. B. Gurdon, *Adult Frogs Derived from the Nuclei of Single Somatic Cells*, 4 DEVELOPMENTAL BIOLOGY 256, 256-73 (1962).

28. See J. L. Hall et al., *Experimental Cloning of Human Polyploid Embryos Using an Artificial Zona Pellucida*, 60 FERTILITY & STERILITY, Oct. 1993, at S1 (Conjoint Meeting of the American Fertility Society & the Canadian Fertility & Andrology Society, Oct. 11-14, 1993); see also Nat'l Advisory Board on Ethics in Reprod., *Report on Human Cloning Through Embryo Splitting: An Amber Light*, 4 KENNEDY INST. ETHICS J. 251, 251 (1994).

29. The scientists who cloned Dolly by nuclear transfer had failed in their previous 276 attempts and she was born with the biological age of the sheep being cloned. See Philip Cohen, *Bad Copies: Do Some Clones Lose Something Vital During Their Creation?*, NEW SCIENTIST, Feb. 3, 2001, at 7, 7. See generally Roslin Institute, at <http://www.roslin.ac.uk> (last modified May 31, 2001).

30. See Hall et al., *supra* note 28.

31. Commentary at the time was mainly confined to the technical scientific papers in which the technique was described, and since that time the process appears not to have attracted wider critical attention.

32. See Alison Abbott, *Trepidation Greets Plan for Cloning Humans*, 410 NATURE 293, 293 (2001).

reproductive age. As already indicated, there are still many unresolved scientific difficulties with the technique, which it thus seems grossly premature to apply to humans. But even apart from the technical difficulties, are humans in danger of being perceived, in the language of sustainable development, as renewable resources? If renewable, is a human somehow less human, and what might the Constitution tell us about this? And what of the humanity or personhood of the clones?

The British Parliament recently voted to allow cloning of human embryos, up to fourteen days of development, for the purpose of facilitating stem cell research and what might be described as the *sustainable development* of humans in terms of finding cures for Parkinson's disease and other highly debilitating illnesses.³³ Human cloning for the purpose of "harvesting" renewable parts—*spare parts*—has already been mooted. Here again we see a concept of sustainability under consideration outside the agricultural context. Effectively headless frogs have already been produced and cloned to show what might be done in this regard.³⁴ The headlessness of the creature is thought by some to render less objectionable or offensive the harvesting of its parts and those of its creature clones. Should we equate the possession of a functioning brain with being human? We have never regarded anencephalic babies, those born without brains, and which often survive for several days, as less than human. This presupposes that we can clearly define a *human* brain in this new age of transgenic animals.

The Fourteenth Amendment gives a right to life, liberty, property and to equal protection of the laws.³⁵ Is this a right to a life as opposed to a life shared, however equally or unequally, with clones? It is clear that we do not regard identical twins as less than fully and independently human. Interesting questions could also arise with regard to the pursuit of a private and family life. Countenancing the *patenting* of human beings or human embryos in the United States, and thus turning them into intellectual property, could well be regarded as contrary to the Thirteenth Amendment's prohibition on slavery, and in Europe the

33. Compare President George W. Bush's ban on August 9, 2001 of federal funding for work on cell lines ~~other~~ than those already in existence. See Katharine Q. Seelye, *Bush Gives His Backing for Limited Research on Existing Stem Cells*, N.Y. TIMES, Aug. 10, 2001, at A1. Since President Bush made his announcement, it has come to be more widely understood that although over 60 cell lines are in various stages of production, less than a dozen of these may be suitable for use in human trials. See generally *Comm. on Health, Educ., Labor and Pensions: Hearing on Stem Cell Research*, 107th Cong. (2001) (prepared testimony of Douglas Melton, Professor in the Natural Sciences, Harvard University).

34. See Oliver Morton, *First Dolly, Now Headless Tadpoles*, 278 SCIENCE 798, 798 (1997).

35. U.S. CONST. amend. XIV; see also U.S. CONST. amend. IV; U.S. CONST. amend. V.

equivalent provisions of the European Convention for the Protection of Human Rights and Fundamental Freedoms.³⁶ But lest it should be thought that this is too futuristic, patent applications involving humans have already been made in several jurisdictions and legislatures are under pressure to facilitate such developments. The Newman patent application, claiming numerous varieties of human-animal hybrids, or chimeras, failed,³⁷ among other reasons, because it did not meet the non-obviousness requirement of patent law and because it failed to make sufficient enablement and best mode disclosures. The patent office discussed the fact that such a patent might be immoral if the ratio of human to non-human animal genes was too great (here the ratio was not specified with sufficient precision) but, having decided that a human being as such was not patentable, the patent office came to no clear conclusion on where it would draw the line in terms of determining the humanness of an invention. The Patent and Trademark Office (PTO) statement was worded so as to leave open the way for continuing to grant patents on transgenic animals such as the transgenic pigs that overwhelmingly possess pig rather than human genes. What proportion of human genes will be required before the PTO will decide that a claimed chimeric invention is essentially human?

III. BIODIVERSITY AND BIOPIRACY

A. *Hidden Hazards*

Environmental concerns center mostly on the protection of biodiversity. Biodiversity can be damaged as a result of the introduction of modified plants and animals or smaller organisms that may have unexpected and harmful interactions with the environment. Biodiversity issues must not be underestimated as we learn that biotechnologists are altering the natural course of evolution, not only for humans but also for the entire ecosystem. Legislative bodies can isolate specific harmful inventions and techniques and outlaw those while providing for strict testing procedures for new inventions, with legal sanctions for inventions that cause harm despite the testing. In this latter context, we must remember that in this age of globalization and technology transfer a recipient nation may receive

36. European Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 1, 1998, <http://www.echr.coe.int/Convention/webConvenENG.pdf>.

37. Mark Jagels, *Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115, 115-16 (2000).

much more than it wishes or bargained for when it imports organisms or organic material from overseas. Various countries are now concerned not only about hoof and mouth disease, but about cattle and cattle embryos imported from the United Kingdom at the height of the Bovine Spongiform Encephalopathy (BSE) or “mad cow” epidemic. The potential for BSE in livestock imported from Europe gives some indication of just what might be exported and imported in seemingly environmentally sound livestock. Similarly, when patent depositories and other organic banks are drawn upon in the future, perhaps, as already noted, for medicinal purposes or for the reconstruction of extinct species, the possibility of contamination of samples or of the existence of retro viruses should not be overlooked. One of the main reasons that the British government has so far prohibited the transfer into humans of hearts from pigs genetically engineered with human genes is concern about the possibility of transfer of undetected and unknown viruses and/or proteins such as the prions thought to be the causative agent in BSE. This is also a matter for serious concern in relation to human stem cells nurtured with bovine blood or mouse cells.³⁸

B. Indigenous Peoples and Farming

The case for caution in the implementation of relatively untested biotechnology on farms is countered by the promotion of advances in biotechnology as a boon for farmers and the people of developing countries. Biotechnological advances in agriculture may indeed improve the productivity of those farmers who can afford to exploit biotechnological inventions. In developing countries where high levels of agricultural production are especially important, biotechnological advances might help to meet the goal of sustainable development by improving the efficiency of land use and increasing the amount of food available. The threat to biodiversity must, it is thought, be balanced against a developing country's need for food. Developing countries that are faced with reduction of agricultural diversity might pass legislation banning genetically modified crops or encouraging farmers, by subsidies or other means, to use traditional materials and methods for farming. Both of these actions, however, might preclude the introduction of beneficial developments.

38. See generally *Comm. on Health, Educ., Labor and Pensions: Hearing on Stem Cell Research*, 107th Cong. (2001) (Most of the existing true stem cell lines eligible for federal funding in the United States have not undergone safety testing and have been mixed with cells from laboratory mice.).

Yet it is the developing countries that have much to offer the developed countries in terms of unspoiled resources and rich gene pools. Developing countries are the primary source of genetic material for use in biotechnological research,³⁹ as well as the primary targets for the sale of the fruits of that research. The introduction of biotechnology into developing countries may potentially allow the developing countries to develop in ways that are more sustainable and less damaging to the environment than those used by the developed countries. This may, however, come at the expense of traditional knowledge and innovations in the developing countries.

Indigenous cultures in the developing world have had little need in the past for intellectual property protection. In a rural society, in which innovation occurs primarily through traditional, biological means, inventiveness in agriculture is tied to physical property in such a way that knowledge can be transferred without harm to the transferor's income. When a farmer spends time breeding a better seed the result is a collection of physical property—seeds—that can be used in the next season and sold to neighboring farmers for their own use. The seeds have more value to the neighboring farmers than mastery of the particular breeding process that produced them because the seeds will reproduce themselves more quickly than would occur through the application of the process that created them. In this traditional society, all farmers benefit from the spread of knowledge and the sale of new and better seeds.

When private parties from developed countries come into developing countries to exploit their biodiversity, the rights of traditional cultures to their resources, knowledge, and means of innovation are threatened. A company may, for instance, visit a traditional farmer and purchase a sample of the finest seeds he has produced. The company may then take these seeds to a laboratory, study their genetic composition, perhaps alter them slightly, and then apply for a patent.

The company may then come back to the traditional farmer and his neighbors, prohibit them from using the seeds that are now patented, and sell the company's seeds to the farmers as a substitute. The farmer will have lost the use of his original seeds and the right to create new breeds from the company's seeds for sale to his neighbors. The same pattern may occur in the field of pharmaceuticals. A company may discover that indigenous people are using a

39. Thomas Cottier, *The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law*, in *THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENT AND MATERIALS: PART 2* 1820, 1828 (Frederick Abbott et al. eds., 1999) ("It is reported that some 90 percent of genetic information and traditional knowledge is to be found [in developing countries].").

certain plant to treat a rash. The company may take a sample of the plant, create a lotion from it, patent it, and take away the indigenous culture's right to use their own treatment unless it is purchased from the company.

In order to promote sustainable development, an intellectual property protection plan should incorporate provisions that would prevent this kind of biopiracy. Abuses are possible because intellectual property protection is foreign to traditional cultures in developing countries. These cultures rely on shared knowledge to support the community's welfare. The sudden introduction of a patent system places these cultures at a terrible disadvantage in relation to international corporations, because indigenous people often cannot or do not wish to pay for international patent protection for their biological resources.

First, the interests of developing countries in their biological resources must be appreciated and protected. These countries must have some control over the transfer of their resources to the use of more developed countries, and they must be compensated for the loss of resources as well as rewarded for any benefits provided by their use. Next, traditional means of innovation must be protected to promote biodiversity and to sustain traditional cultural heritage. At the same time, developing countries must have access to biotechnological inventions that will help them to feed and treat their people and to develop.

The European Directive on the patenting of biotechnological inventions⁴⁰ addresses these goals—the need for effective biotechnology transfer and the protection of resources and traditional innovation—in its Preamble and articles. Paragraph eleven of the Preamble asserts the importance of biotechnology to the health and nourishment of developing countries and calls for the promotion of “international procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned.”⁴¹ The Preamble also incorporates article 16(2) of the Convention on Biological Diversity,⁴² which states, “[T]ransfer of technology . . . to developing countries shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed.”⁴³ The actual articles of the European Directive do not affirmatively promote the transfer of biotechnology, but they do provide some protection for farmers—protection that may encourage

40. Council and European Parliament Directive 98/44/EC, 1998 O.J. (L 213) 13.

41. *Id.* pmbl. 11.

42. *Id.* pmbl. 55; *see also* United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, art. 16(2), 31 I.L.M. 818, 829 [hereinafter CBD].

43. CBD, *supra* note 42, art. 16(2), at 829.

them to purchase protected materials. The European Commission apparently intended to allow the producers of biotechnology to control transfer, while it protected the farmers from certain kinds of abuse. This protection comes in the form of derogation rights for the farmers. When a farmer purchases patented seeds or livestock, article eleven of the Directive provides that the farmer will be given the right to use the product of a harvest or the offspring of livestock for replanting or further breeding.⁴⁴ This derogation is subject to the provisions of the 1994 Council Regulation on Community plant variety rights (Regulation on plant variety rights).⁴⁵ The Regulation allows the holders of plant variety rights to charge a fee for derogation, but small farmers are excluded.⁴⁶ Fortunately, most of the farmers in developing countries who would not be able to pay this fee fall into the category of small farmers.

Producers of biotechnology may still be able to prevent the use of future generations of seeds by using so-called "terminator technology," which renders sterile the second generation of crops.⁴⁷ Monsanto has, however, withdrawn its terminator seeds. Perhaps this was in part because many farmers in developing countries cannot afford to purchase new materials every year and the market may well have extinguished the use of the technology as companies that did not use it gained a competitive advantage.

The Directive is less protective of developing countries' rights to control the use of their genetic resources, traditional knowledge, and innovation. Its Preamble incorporates articles from the Convention on Biological Diversity that promote the protection of developing countries' rights.⁴⁸ Paragraph fifty-six also reasserts the statement, from the Third Conference of the Parties to the Biodiversity Convention, that:

[F]urther work is required to help develop a common appreciation of the relationship between intellectual property

44. Council and European Parliament Directive, *supra* note 40, art. 11(1) (discussing the sale of seeds) & 11(2) (discussing the sale of livestock).

45. Council Regulation 2100/94, 1994 O.J. (L 227) 1 (covering European Community plant variety rights).

46. *Id.* art. 14(3).

47. Kojo Yelapaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 32 *MCGEORGE L. REV.* 111, 171-74 (2000).

48. CBD, *supra* note 42, art. 3, at 824 ("States have . . . the sovereign right to exploit their own resources pursuant to their own environmental policies"); *id.* art. 8(j), at 826 ("[each party shall] respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity . . . and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.")

rights and the relevant provisions of the TRIPS Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.⁴⁹

The required work has not been forthcoming and article eight of the Directive extends patent protection to “biological material derived from” patented material⁵⁰ or from material created by a patented process.⁵¹ Although the derogation provided by article eleven allows farmers to avoid the article eight protection when using seeds or livestock on their own farms, it does not allow them to sell future generations of seeds or livestock. When farmers develop new innovations through traditional breeding, using material that is protected by patent, they cannot exploit this innovation except on their own farms.

Finally, a few words about the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The main objective of that agreement was to harmonize and strengthen the global protection of intellectual property. In general, TRIPS requires that patents be available without discrimination as to subject matter, but an exception is made in relation to some types of biological inventions. As we have seen, article 27(2) of TRIPS provides that

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such

49. Council and European Parliament Directive, *supra* note 40, pmbl. (56) (quoting Decision III/17 of the Third Conference of the Parties to the CBD (Nov. 1996)).

50. *Id.* art. 8(1) (“The protection conferred by a patent on a biological material . . . shall extend to any biological material derived from that biological material.”).

51. *Id.* art. 8(2) (“The protection conferred by a patent on a process that enables a biological material to be produced . . . shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material.”).

exclusion is not made merely because the exploitation is prohibited by domestic law.⁵²

Under article 27(3),

Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.⁵³

It is also very important to note in this context that article 31 of TRIPS places severe restrictions on the granting of compulsory cross-licenses, a position which is entirely consistent with the antipathy generally displayed in TRIPS towards restrictions on patent holders' rights.⁵⁴

In any attempt to renegotiate these provisions of TRIPS, attention must be devoted to the importance of protecting biodiversity and of sharing the benefits of innovation with the countries that provide the biological resources. Yet it seems that the developed nations will not lightly concede less than the widest possible intellectual property protections. These and other tensions led to street protests and a failure by the developed and developing countries to reach agreement during the World Trade Organization talks in Seattle at the time of the 1999 review. In the light of the competing needs and interests we have noted, this was perhaps not surprising. Some of the parties involved bridle at the notion that patent offices around the world are patenting organisms that can more fairly be regarded as products of nature rather than man and as pure discoveries rather than

52. See TRIPS Agreement, *supra* note 9, art. 27(2).

53. See *id.*, art. 27(3).

54. See Yvonne Cripps, *Aspects of Intellectual Property in Biotechnology: Some European Legal Perspectives*, in PROTECTION OF GLOBAL BIODIVERSITY: CONVERGING STRATEGIES 316, 325 (Lakshman D. Guruswamy & Jeffery A. McNeely eds., 1998).

inventions. Especially notable in this regard are the patents that have been granted on the nucleotide sequences of human genes and the applications that have been filed and granted in relation to the genes of particular tribes.⁵⁵ We are, in some cases, annexing and patenting the common heritage of mankind, and, more recently, mankind itself.

CONCLUSION

The concept of sustainable development has always been ill defined, some would say empty, but there has been consensus about its context. It has been assumed that the topic is confined to agriculture. This was a logical assumption at the time the concept first became prominent in the mid-1980s. Since then, the rapid development of the technologies of genetic modification and cloning and the patenting of genetically modified animals, human gene sequences, and stem cells impel us to consider the concept of sustainable development in novel contexts that include the cloning of creatures and embryonic stem cells for use as spare parts. Perhaps this new world is neither brave nor sustainable, but it involves issues that lawyers and policy makers would be very unwise to neglect.

55. See U.S. Patent No. 5,397,696 (issued Mar. 14, 1995); Debra Harry, *The Human Genome Diversity Project: Implications for Indigenous Peoples*, Mar. 14, 1995, at <http://www.hartford-hwp.com/archives/41/024.html>.

